

K051528

JUL 20 2005

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:  
June 5, 2005

Submitter's Information: 21 CFR 807.92(a)(1)

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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name: MeVis LiverAnalyser / LiverViewer Software™  
Common Name: Picture Archiving Communications System  
Device Classification: 892.2050 LLZ  
Name: System, Image Processing

Predicate Device: 21 CFR 807.92(a)(3)

Device Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Regulation Number	892.2050	892.2050
510(k) Number	K022692	K040852
Device Name	VoxelPlus PACS	Preview Treatment Planning Software
Applicant	Mevisys Co. Ltd.	Medical Media Systems, Inc.
Product Code	LLZ	LLZ

Device Description: 21 CFR 807.92(a)(4)

MeVis LiverAnalyser / LiverViewer Software™ is a PC-based software application that imports medical images (i.e. CT, MRI modalities) in a DICOM format. The MeVis-LiverAnalyser is used to analyze data for preoperative planning in liver surgery. The MeVis-LiverAnalyser contains dedicated methods for organ segmentation, tumor segmentation, and segmentation of intrahepatic vasculature as well as for the approximation of vascular territories. While using the MeVis-LiverAnalyser a number of masks are produced to merge voxels into sets. Each of this set is meant to represent a specific anatomical entity. All volumes calculated by the MeVis-LiverAnalyser are given directly by the number of voxels in one of these sets multiplied by the voxel volume. No direct measure of anatomical entities is performed.

**Indications for Use: 21 CFR 807 92(a)(5)**

The MeVis LiverAnalyzer / LiverViewer Software™ device is intended for preoperative planning in liver surgery. The device is used to analyze data and to display image analysis and risk analysis results for the preoperative planning in liver surgery, e.g. organ segmentation, tumor segmentation, segmentation of intrahepatic vessels as well as the approximation of vascular territories. Preoperative evaluation of specific surgery strategies is supported by the feature to interactively define virtual resections splitting the liver or to calculate safety-margins around lesions identifying affected vascular branches and vascular territories supplied or drained by these branches.

Medical image data is derived from various sources (i.e. CT scanners, MRI scanners). Typical users of this system are trained professionals, including physicians, nurses, and technicians.

**Technological Characteristics: 21 CFR 807 92(a)(6)**

MeVis LiverAnalyser / LiverViewer Software™ is a software product that assists surgeons when doing preoperative planning and post-operative follow-up. MeVis LiverAnalyser / LiverViewer Software™ is a PC-based software application that imports medical images (i.e. CT, MRI modalities) in a DICOM format.

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

**Conclusion: 21 CFR 807 92(b)(1)**

The 510 (k) Pre-Market Notification for MeVis LiverAnalyser / LiverViewer Software™ device contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

MeVis LiverAnalyser / LiverViewer Software™ device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "minor".



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 20 2005

MeVis – Center for Medical Diagnostic  
Systems and Visualizations GmbH  
% Mr. Carl Alletto  
1600 Manchester Way  
CORINTH TX 76210

Re: K051528  
Trade/Device Name: MeVis LiverAnalyser/  
LiverViewer Software  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: May 11, 2005  
Received: June 15, 2005

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K051528

Device Name: MeVis LiverAnalyzer / LiverViewer Software™ device

## Indications for Use:

The MeVis LiverAnalyzer / LiverViewer Software™ device is intended for preoperative planning in liver surgery. The device is used to analyze data and to display image analysis and risk analysis results for the preoperative planning in liver surgery, e.g. organ segmentation, tumor segmentation, segmentation of intrahepatic vessels as well as the approximation of vascular territories. Preoperative evaluation of specific surgery strategies is supported by the feature to interactively define virtual resections splitting the liver or to calculate safety-margins around lesions identifying affected vascular branches and vascular territories supplied or drained by these branches. Medical image data is derived from various sources (i.e. CT scanners, MRI scanners).

Typical users of this system are trained professionals, including physicians, nurses, and technicians.

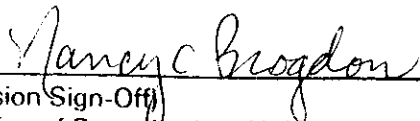
Prescription Use ☒   
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐   
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K051528